PTO 06-1145

CY=WO DATE=19930401 KIND=A1
PN=93-05733

LENS IMPLANT
[IMPLANT CRYSTALLINIEN]

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UNITED STATES PATENT AND TRADEMARK OFFICE
Washington, D.C. December 2005

Translated by: FLS, Inc.

PUBLICATION COUNTRY	(10):	WO
DOCUMENT NUMBER	(11):	93/05733
DOCUMENT KIND	(12):	A1
PUBLICATION DATE	(43):	19930401
APPLICATION NUMBER	(21):	PCT/FR92/00896
APPLICATION DATE	(22):	19920925
INTERNATIONAL CLASSIFICATION	(51):	A61F 2/16
PRIORITY COUNTRY	(33):	FR
PRIORITY NUMBER	(31):	91/11810
PRIORITY DATE	(32):	19910925
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DESIGNATED CONTRACTING STATES	(81):	CA, JP, RU, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE)
TITLE	(54):	LENS IMPLANT
FOREIGN TITLE	[54A]:	IMPLANT CRYSTALLINIEN

Lens Implant /1*

The invention concerns a lens implant intended for correcting ametropy due to the loss of the surgically removed lens diopter.

The extra-capsular extraction of the cataracted lens and the implantation of an artificial lens into the capsular sack have become the principle method of treating cataracts in recent years. The surgical procedure most used is called extra-capsular extraction. It consists in removing the core and the lens cortex after having made an opening in the anterior part of the capsule enclosing them. The extraction is often performed manually by the surgeon or by means of a technique called phacoemulsion. As compared with manual extraction, the latter technique has the advantage of a small incision in the corneo-scleral wall of the eye. In fact it is known that a small incision has fewer risks of clinical or optical complications.

The disadvantage of a small incision is that it does not accept all implants and, in particular, rigid implants, the diameter of which is often greater than the length of the incision. This is why, if the surgeon decides to insert a rigid implant made of polymethyl methacrylate, he proceeds to enlarge the corneal incision. However, in the majority of cases, in order to preserve the small size of this corneo-scleral incision, foldable, flexible implants, which are placed in the lens capsule, are introduced.

There are several types of flexible implants capable of being inserted folded, and unfolding in the interior of the capsule. Their

*Numbers in the margin indicate pagination in the foreign text.

principle disadvantage is the fact that the support of this implants at the level of the equator of the capsule is not uniform and this capsule wrinkles progressively, which results in reducing vision and finally requires a secondary intervention which consists in laser destruction of the center of the rear part of the lens capsule /2 (posterior capsule). In addition, these implants, precisely because of the imperfect fixation in the capsule, can shift which results in an alteration of the vision since the optical zone is decentered.

US A 4 946 469, which describes an intracapsular implant in which the optical part is surrounded by an extremely supple support part in order to tightly enclose the posterior capsule, will be cited in order to illustrate this prior art. This sort of very supple skirt cannot give satisfaction for correct holding of the implant. In fact, it is known that after extraction of the core and lens fibers the posterior capsule tends to be shifted forward. This movement has the effect of wrinkling this capsule, in particular in the optical zone, which, according to this document, prevents the implant from correctly hugging the interior surface of the posterior capsule. Therefore the risks of cellular growth between the capsule and the implant of the fibrous type, which in the course of time will alter the quality of the view. This growth can lead to a deformation and shifting of the implant. In addition, the extreme suppleness of the skirt of the implant does not seem to be capable of constituting a means of holding sufficient to assure against the risks of luxation of the implant, or its expulsion to the exterior of the capsule. In the case where the

lens is rigid, no accommodation is possible.

In addition, there is a need, not satisfied by current intraoccular implants, for restoring the accommodation abilities of a patient who has had a cataract surgically removed.

All the implants currently used do not take account of the fact that the extra-capsular extraction can preserve the accommodation capabilities of the cataract surgery patient. In fact, it seems that the hardening of the lens core is the principle cause of the far-sightedness, as opposed to the deformation of the natural crystalline lens under the effect of the contraction and decontraction of the /3 ciliary muscle, rather than the alteration of this muscle or the zonule.

Thus when the capsular sac is preserved at the time of the operation, all the means of accommodation are equal. Certain implants described in the literature claim to use the deformation of the capsular sac in order to change the optical power of the implant. The document EP A 0 337 390 which describes an implant possessing two optical parts separated from one another by a deformable element and the distance of which can vary with the action of ciliary muscle on the capsular sac by the intermediary of the zonular fibers. The structure of this implant is complex, and difficult to manipulate for placing it in the eye.

The present invention is intended to remedy the disadvantages of the flexible implants by offering a possibility of accommodation, with simpler means than those known up to now.

First it must be recalled that the accommodation is for the natural lens the result of a modification of its anterior and posterior curves as well as its position in the optical system of the eye (between cornea and retina). These modifications result from the deformation of the capsular sac on which the zonular fibers connecting it to the ciliary muscle. When these fibers are relaxed, that is when the ciliary muscle is contracted, the lens is in its form and position of rest. The radii of curvature of its anterior and posterior faces are at their lower value and the lens is in its position closest to the cornea. Then the eye accommodates for close vision. On the other hand, when the zonular fibers are stretched because of the relaxation of the ciliary muscle, the capsular sac is slightly stretched toward the exterior, which has the effect of increasing the radius of curvature of the lens, and of causing a slight displacement of the latter toward the rear, that, by moving the cornea further away. /4

The implant according to the invention has the means necessary for the conversion of the action of the ciliary muscle by modifying the power of its optical part.

Therefore, for this purpose the object of the invention is a lens implant made of flexible material having a central optical zone and peripheral means for supporting and centering it in the capsular sac, in which the optical zone is a deformable lens, the posterior face of which is convex, the peripheral means consisting of a peripheral edge, the exterior diameter of which is approximately equal to the equatorial diameter of the capsular sac at rest and of a thin dome

connecting the lens to the peripheral edge, the latter elastically deformably forming a tensioning member of the dome.

The first role of the peripheral edge is to permit the deployment of the implant in the interior of the capsular sac after its introduction in the folded state. It also assures good placement of the latter at the level of the meridian of the sac, since its peripheral length will be chosen to be very close to the length of this meridian so that any risk of luxation or expulsion of the implant is eliminated.

In order to assure this first role, the stiffness of the peripheral edge can be imparted by its shape (for example, a groove of the minor radius of curvature) or by its thickness in order to form a roll.

The dome forms a cover, the surface of which is approximately identical to the surface of the corresponding annular part of the capsular sac, so that the implant perfectly matches this face, exerting a very slight pressure there by which the posterior capsule is held without folds.

In certain embodiments, the part of the dome close to the outer /5 edge can be thicker that that close to the lens where it will be advantageous that it is relatively thin or, equivalently, of a different modulus of elasticity (for example, by radiation treatment of a synthetic material in order to create a more deformable bond between the cover and the lens than a thicker cover would permit. In fact, it is appropriate that the tension of the zonular fibers (at the time of

distance vision with relaxation of the ciliary muscle), which tends to shift the capsular sac forward, causes a pressure on the central part of the implant, therefore on the optical lens, in order for this pressure to cause a modification of its radii of curvature, such that the power of the lens is diminished as will be described in greater detail below, in the description of several possible embodiments.

Reference will be made to the appended drawings in which:

- Fig. 1 is a cross-section of a first embodiment of the invention, placed in a capsular sac in a state of rest,

- Fig. 2 is a partial view of the implant of Fig. 1 illustrating the amplitude of the deformations that it suffers under the effect of the zonular traction,

- Fig. 3 illustrates a second embodiment of the invention by means of an exploded view,

Fig. 4 is a section of a third embodiment of the invention.

The implant of the invention is made of a material having a high refractive index (for example, greater than 1.50) by using melted polymers and copolymers on the polydiphenyl siloxanes that are transparent and biocompatible flexible synthetic materials or hydrogels. This high refractive index permits the construction of a powerful implant having small thickness.

In Fig. 1, the implant 1 has the general form of a hollow ellipsoid of revolution around its minor axis 2. One of the hemispheres 3 has a complete wall while the wall of the other hemisphere has a central opening 4 and is limited to an annular

portion 5 returning to above the complete wall 3. The complete wall 3 has an optical zone 6 forming a lens, for example a biconvex lens, located in the center of the wall. It will be noted that the anterior face of this lens (the latter turned toward the opening 4) may be plane or even concave. This lens is extended by an annular cover 7 in the form of a dome up to the equatorial zone 8 of the implant where the wall forms a groove and is a little thicker than the cover in order to constitute a deformable elastic tensioning member.

This implant is intended to be place in the capsular sac represented by line 9 of Fig. 1.

The zonular fibers 10 are inserted in the capsular sac in the vicinity of the equator of the latter and their actin is approximately directed alone a cone, the point of which is turned toward the front and which is largely open at its tip. The generating lines 11 of this cone is shown in Fig. 3 in the plane of the cross-section.

In addition to its role as a tensioning member of the dome 7 in order to unfold it after it is inserted in the eye, the edge 8 has the function of holding the implant in the sac 9 since it will have been chosen to have an exterior diameter approximately equal to the equatorial diameter of the capsular sac 9. This stiffness resulting from the groove and/or from the excess thickness of the edge 8 and this dimension also making it possible to exert a certain tension on the sac, which suppresses the formation of folds of the capsule. The dome 7 and the optical part 7 therefore are correctly supported on the

posterior wall of this capsular sac. In fact, it is known that this contact is favorable, since it constitutes an effective means of inhibiting the cellular growth in the sac and therefore prevention of /7 the development of a fibrosis that then must be treated, for example, by means of a laser.

Fig. 2 is a diagram that illustrates the behavior of the implant brought about by the zonule.

This figure shows the majority of the elements already described above with the same reference numbers. The solid line shows the implant in its position at rest where it is in contact with the capsular sac 9, the zonular fibers being relaxed. The posterior radius of curvature R_1 of the lens is 18 millimeters here and the anterior one R_2 is 30 millimeters.

A traction F simulating the action of the tension of the zonular fibers was applied to the capsular sac 9 on a mathematical model of the implant, and the implant is deformed up to its position represented with a dotted line in Fig. 2.

The radii of curvature R_1 and R_2 have become $R''_1 = 20.5$ millimeters and $R'_2 = 25.3$ millimeters. The optical zone also has been shifted slightly to the front of the capsular sac. This deformation is explained by the fact that the posterior wall of the capsular sac pulled by circular traction by the zonule exerts a pressure to the front on the implant at the level of the optical lens 6 and of the dome 7 while the more rigid edge 8 is very slightly deformed (slight rotation). Therefore this pressure is translated by

the indicated variations of the radii of curvature and the slight advance of the implant in the direction of the cornea.

Therefore it was possible to calculated that for a refractive index of 1.58, the modification of the shape of the lens and its shift in the optical system of the eye cause a reduction of the power of the artificial lens of around 2 to 3 diopters in distance vision and finds its initial power in close vision (ciliary muscle contracted and zonule relaxed). This finding is surprising since, a priori, two /8 (R_2 and shifting) three parameters (R_1, R_2, and shifting) vary in a sense unfavorable to a decrease in power.

The implant according to the invention is of simpler construction that all of the prior art implants capable of accommodation.

Of course, the shape of this implant at rest is not limited to that shown in Figs. 1 and 2.

In Fig. 3, for example, there not return **5** beyond a roll **8** forming the tensioning member of the dome **7**. In addition, this dome **7** is of variable thickness, the decreasing the periphery **8** toward the lens **6**. Thus, the optical lens has great freedom to be deformed by the pressure caused by the capsular wall pulled by the zonule.

In addition, the dome can have radial stiffening elements **12** that permit the concept of adjusting the rigidity, that is the form of the dome, in order that it be less deformable in the vicinity of the edge and, more and more flexible in the direction of the lens.

Openings **13** are made in the dome in order to facilitate placement.

It will be mentioned that in the plane of the shape itself, the implant can be different from the ellipsoid shown without departing from the framework of the invention. It is possible to mention a shape in which the curvature of the posterior face of the implant will be more pronounced in order to be close to that of the posterior face of the natural lens.

In Fig. 4, the implant shown has a second optical wall **14** in front of the lens **6** that may be a plate having parallel faces or a lens and therefore may participate in the power of the implant. This second wall, which closes the ellipsoid in the front, is provided with openings **15** for liquid circulation in the interior of the implant and for folding thereof. The wall **14** does not suffer deformations /9 because of the tension of the capsular sac since the sac has been opened by is anterior wall, which therefore no longer exists.

CLAIMS /10

1. A lens implant (1) made of flexible material having a central optical zone (6) and peripheral means for its support and its centering in the capsular sac (9) of the eye, wherein the central optical zone is a deformable lens, the posterior face of which is convex, the peripheral means consisting of a peripheral edge (8), the exterior diameter of which is approximately equal to the equatorial diameter of the capsular sac at rest and by a dome (7) of small thickness connecting the lens (6) with the peripheral edge (8), the latter elastically deformably forming a tensioning member of the dome (7).

2. The implant according to Claim 1, wherein the thickness of the dome (7) decreases between the edge (8) and the lens (6).

3. The implant according to Claim 1 ore Claim 2, wherein the dome is provided with radial stiffening elements (12) in the vicinity of its peripheral edge (8).

4. The implant according to any of the preceding Claims, wherein it consists of an approximately ellipsoidal hollow body, one of the walls of which bears the lens (6) and the dome (7), the other wall (14) being provided with openings (15), the walls being connected by their exterior edge (8) forming a tensioning member of the dome (7).

5. The implant according to any one of the preceding Claims, wherein the peripheral edge (8) is in the form of a groove.

6. The implant according to any one of the preceding Claims, wherein the peripheral edge (8) is in the form of a roll or a excess thickness of the wall.

FEUILLE DE REMPLACEMENT=REPLACEMENT PAGE

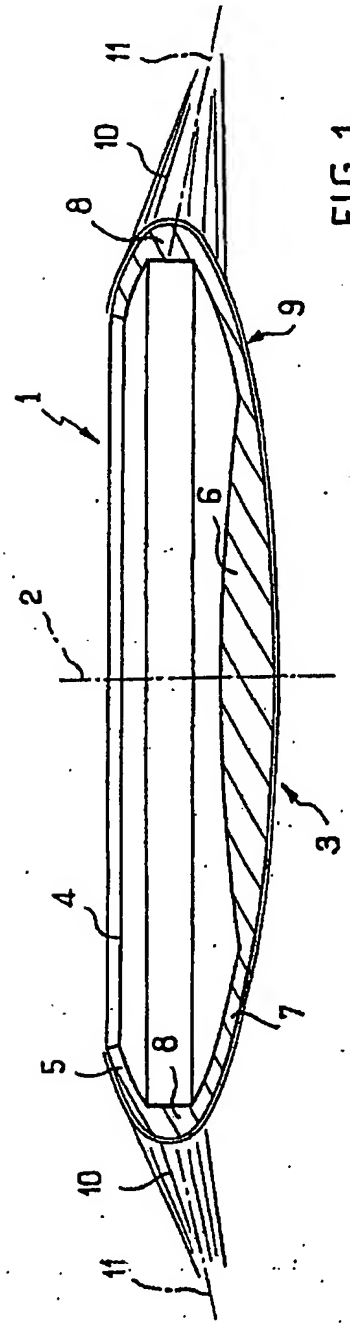

FIG.1

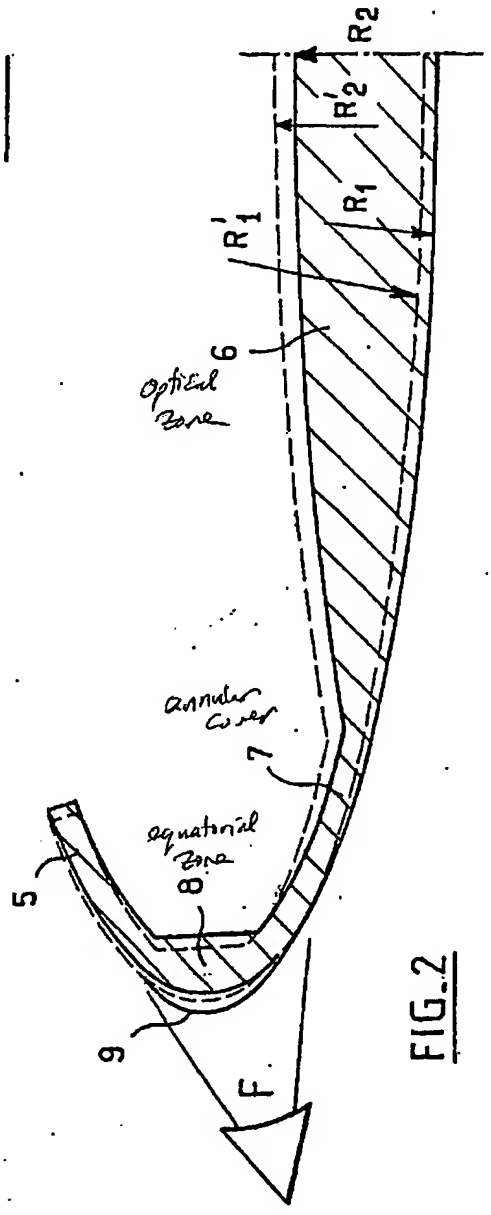

FIG.2

FEUILLE DE REMPLACEMENT

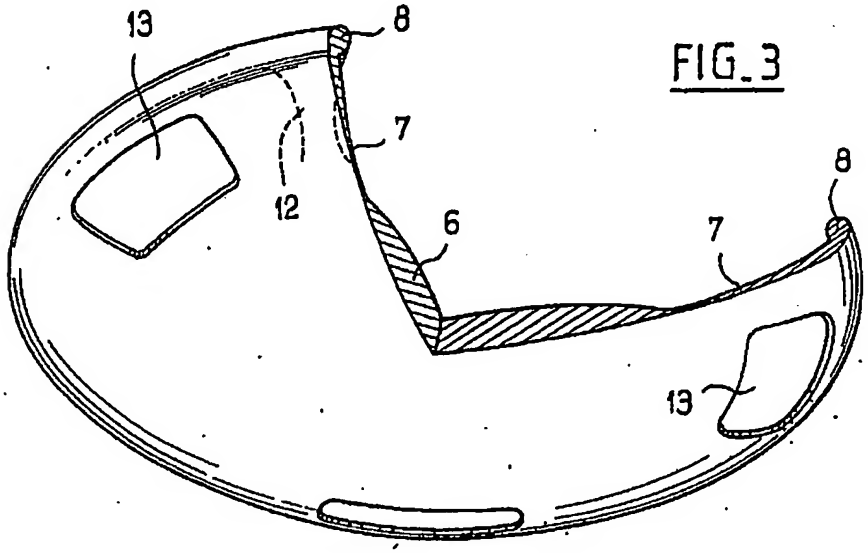

FIG_3

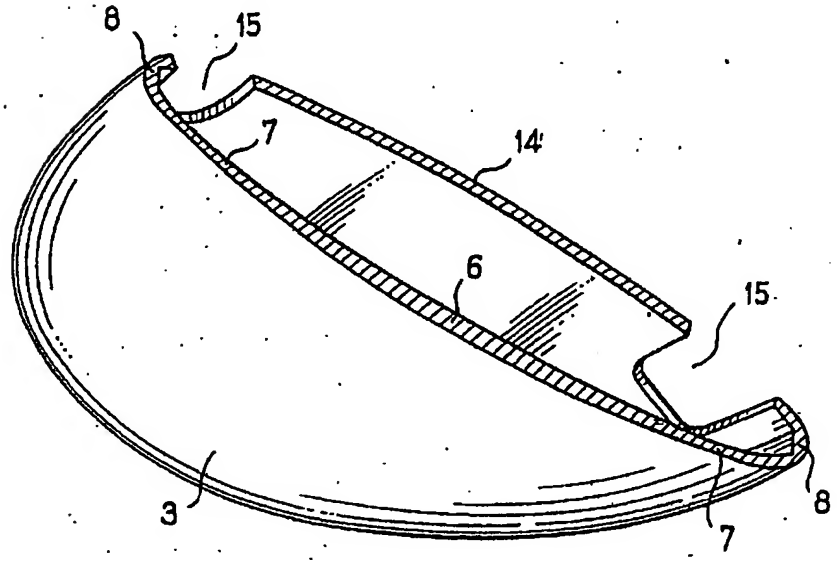

FIG_4